EUR*Observational* Research Programme

Protocol

Long-Term Registry on Patients with Heart Failure

March 29th, 2011

Revised October 17th, 2013

version 2.0

Study sponsored by the European Society of Cardiology

Executive Committee:

Members listed in Appendix 1

Coordinating centre:

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Protocol history

Protocol version Number	Protocol Version date	Amended pages	Changes
1.0 (missing in the footer of the protocol)	29 Mar 2011	Not Applicable	Not Applicable (first Version)
2.0	17 Oct 2013	Page 1 and 6	New Executive Committee members now listed in Appendix 1
		Page 7	New Oversight Committee members now listed in Appendix 2
		Page 7	Participating countries and National Coordinators as of October 2013 listed in Appendix 3
		Page 7	EORP team now listed in Appendix 4
		Page 3 and 8	New enrolment scheme: Since October 2013 (Phase 2) patients will be enrolled five consecutive working days per trimester instead of one-day per week previously (Phase 1)
		Page 6	Ivabradine was added to the reasons for non prescription of drugs with a level of recommendation I
		Page 6	The minimum sample size estimated to 10, 000 enrolled patients, is now estimated to 10,000 enrolled patients every 1.5 to 2.0 years
		Page 8	"If a centre does not perform properly, it will be excluded ~~after two months~~ and substituted with another centre."
		Page 8	DURATION OF REGISTRY has been updated: "It is anticipated that approximately 10 000 patients will be enrolled within 18 months. Recruitment of further patients for the ESC-HF Long-term Registry (Phase 2) should begin in October 2013 and the 1-year follow-up should be completed in May 2016"
		Page 10	Updated Proposed Time plan now in Appendix 5
		Appendix 1	The Template of the Informed Consent Form has been removed from the protocol as it is considered as a separate document

Of note, changes in the protocol appendices will not be subject to protocol amendments, in particular with the list of the members of the registry committees as these are subject to regular changes. The functions represented in these committees will however not change.

TABLE OF CONTENTS

1. BACKGROUND AND RATIONALE

Chronic Heart Failure (HF) is associated with a high burden of mortality and morbidity, reduced quality of life and increasing healthcare costs in both US and Europe (1-4). Evidence-based medicine represents the most effective means of ensuring that patients receive high-quality care and appropriate pharmacological/non-pharmacological management (5-7). With the increased prevalence of chronic HF, there is a concomitant increase in the number of related hospitalizations and, as chronic HF progresses, the risk of acute exacerbation increases. Acute HF is a complex, heterogeneous, clinical syndrome characterized by a rapid onset of signs and symptoms secondary to abnormal cardiac function, and it is often life threatening, requiring urgent therapy (8-11). In the United States, a primary diagnosis of acute HF accounts for more than one million hospitalizations each year, with similar numbers suggested for Europe (2,8,9). Despite significant advances in diagnosis and therapy obtained over the past 20 years, patients with HF continue to have a poor long-term prognosis (10,12-15). Clinical destabilizations leading to hospitalization are associated with hemodynamic and neuro-hormonal alterations, which can contribute to progressive ventricular dysfunction and dilation, mitral regurgitation, increased wall stress, and progressive myocyte loss as a result of apoptosis and necrosis (8). Registries and surveys have been conducted in patients with either chronic HF or acute HF but a description of the whole clinical history of patients with HF, including the acute episodes and the consequent changes in clinical conditions and in the management strategies are not available (16,17). A registry able to capture all the relevant clinical information of patients with HF, including their acute episodes of decompensation, would enable us to improve our knowledge on epidemiology and outcomes of real world patients with this clinical condition. Further, specific questions of high clinical relevance could be answered using the information collected in the registry.

2. STUDY DESIGN AND METHODS

The ESC-HF Long-term Registry is a prospective, multicentre, observational study of patients presenting to Cardiology Centres in European and Mediterranean countries. Site selection in each participating country will target a sample of hospitals of different levels of complexity from which patients will be recruited, focusing on capturing a broad spectrum of cardiology and HF specialty units regularly following outpatients with HF and admitting patients with acute, pre-existing or new onset HF in order to build-up a network of centres representative of European reality.

To facilitate consecutive enrolment, since October 2013, patients will be enrolled in the registry on a five consecutive working days per trimestre (phase 2) basis and followed up for at least once a year. Outpatients' visits will be performed according to the usual practice of the participating centres. A visit 12 months after the entry visit is mandatory in order to collect information on morbidity and mortality. A phone call can replace the follow-up clinical visit, in case of impossibility for the patient to reach clinical centres, for logistic reasons, for example.

The primary objective of this registry is to describe the clinical epidemiology of outpatients and inpatients with HF and the diagnostic/therapeutic processes (including the organization of HF management programmes) applied to these patients across Europe and Mediterranean countries.

Standard management of patients will be the diagnostic and therapeutic interventions currently performed in each centre for patients presenting with signs and symptoms of chronic HF/acute HF. Drug prescriptions and indications to perform diagnostic/therapeutic procedures will be completely left to participating cardiologists' decision. No specific protocols or recommendations for evaluation, management, and/or treatment will be put forth during this observational study. Current guidelines for the management of chronic HF/acute HF will be discussed during the Investigator meetings, and doctors participating in the registry, should be adherent to them. In this context, the following topics have been considered as particularly relevant for assuring an adequate care of the patients:

- Documented definition of the etiology,
- Completeness of neuro-hormonal therapy,
- Timing and doses of i.v. drug treatments during the acute phases of HF,
- Appropriate indication for device implantation,
- Data collection on the most important outcome's predictors.

3. SPECIFIC AIMS OF THE STUDY

- To describe the demographic, clinical, and biological characteristics of outpatients and inpatients with HF followed by a representative setting of cardiology centres.
- Specific attention will be focused:
    - on patients with preserved EF, whose heterogeneity in trials and in observational studies needs to be better understood (18-20);
    - on clinically relevant co-morbidities, such as COPD and diabetes mellitus, which frequently are associated with heart failure and impact patient outcomes (21-24).
- To describe the diagnostic and therapeutic approaches undertaken in the routine practice of cardiologists in following outpatients with chronic HF or during the hospital phase for acute HF.
- To assess the in-hospital and out-of-hospital outcomes of patients with HF and to validate the prognostic predictors of these outcomes.
- To evaluate the organization of HF management across Europe and Mediterranean countries.
- To evaluate how recommendations of most recent European guidelines regarding pharmacological and non-pharmacological treatments are adopted in clinical practice and how their application can impact on patients' outcomes (mainly hospitalization for HF). More specifically, information on the reasons why evidence-based treatments are not utilized or under-dosed with respect to the dosages recommended by guidelines will be collected.
- To evaluate the prevalence of the clinical profiles of patients with acute HF, according to the definitions proposed by the European Society of Cardiology (5), and to investigate their appropriateness in characterising patients with different clinical presentations and needs. A focused data collection will be performed in patients with cardiogenic shock, whose lethality rate remains unacceptably high despite the advances in management and treatment implemented in the last decades (25).

4. SELECTION OF STUDY POPULATION

- All outpatients with HF seen at the clinics, and those admitted for acute, pre-existing or new onset HF to participating centres during the enrolment period.
- *Chronic Heart Failure*: every outpatient with chronic HF diagnosed, according to the clinical judgment of participating centres' responsible cardiologists, will be entered in the registry. There are no specific exclusion criteria, with the exception of age that should be over 18 years.
- *Acute Heart Failure:* patients admitted to hospital for acute HF for whom an IV therapy for HF (inotropes, vasodilators or diuretics) is needed.

No data will be collected before detailed information is given to the patient and a signed informed consent is obtained.

Therefore during the course of the screening day:

- All patients seen in the outpatient clinic will be included.
- All patients admitted for acute HF from 0:00AM to 23:59PM (in the same day) will be included.

This enrolment plan along with the predefined typology of the enrolling centres (see below) should reasonably guarantee both consecutiveness and representativeness of the population.

5. DATA COLLECTION

Data will be collected by using a web based system.

5.1 Enrolment data

The following information will be captured for each enrolled patient:

- demographic characteristics
- risk factors for cardiovascular diseases
- co-morbidities
- precipitating factors of acute HF
- clinical signs and symptoms
- biohumoral profile
- use of pharmacological treatments
- reasons for non prescription of drugs with a level of recommendation I, level of evidence A (ACE-I/ARBs, beta-blockers, aldosterone antagonists and Ivabradine)
- reasons for non prescription of recommended dosages of the same drugs (ACE-I/ARBs, beta-blockers, aldosterone antagonists and Ivabradine)
- use of non pharmacological treatments
- reasons for non implantation of devices recommended by ESC guidelines with level of recommendation I, level of evidence A, in patients meeting the indication criteria
- use of invasive/non invasive diagnostic procedures

5.2 Follow-up data

A follow-up visit after 12 months will be scheduled for all outpatients and for patients discharged after an admission for acute HF. During the course of the year patients will be followed-up, according to the usual practice of the centres.

6. STATISTICAL CONSIDERATIONS AND SAMPLE SIZE

All the patients enrolled will be included in the analyses. Since this is an observational study, descriptive summaries will be presented for all the patients, and for subgroups of patients. Statistical tests may be carried out for exploratory purposes, as appropriate. Multivariable analyses may be used to explore relationship between baseline covariates and post-baseline endpoints, as appropriate. The study being fully observational, a formal sample size was not calculated.

However, a sample of 10, 000 enrolled patients every 1.5 to 2.0 years has been estimated as a minimum number to fulfil the level of quality to assess at continental level the profile of both acute and chronic HF patients, according to the collected information listed above. Specifically, the inclusion in the registry of such a number of patients should allow to have sufficient information on a few subgroups of patients for whom a specific focus has been planned (i.e. patients with preserved EF, patients with the different clinical profiles at hospital admission, patients with COPD or diabetes).

The registry is a Long term registry and as such, enrolment of patients will continue largely above 10 000 patients as justified by the scientific purpose of this registry.

7. STUDY ORGANIZATION

7.1 Executive Committee

Members listed in Appendix 1.

The Executive Committee will be responsible for the formulation of the study protocol and to oversee its implementation. This committee will report to the Oversight Committee of the ESC. A writing group supervised by the chairman will be formed for the analysis of the data and its publication.

7.2 Oversight Committee

Members listed in Appendix 2.

7.3 Steering Committee

The Steering Committee is composed by the chairman of the study and by the National Coordinator of each participating country. Countries and members are listed in Appendix 3.

The National Coordinators will be responsible for contact with the investigators at national level and for the implementation of the protocol in their country. They will help translating the patient consent form and any relevant documents for the ethics committees and the relevant national authorities in order to obtain approvals for the registry. They will also assist in the selection of the centres for the registry and in updating the European Society of Cardiology and the investigators with the ethical and legal requirements with regards to the registry in their country, and will ensure performance of the enrolling centres, and quality of national data.

7.4 European Society of Cardiology Coordinating Centre

The EURObservational Research Programme (EORP) Scientific Secretariat and Data Management Team is listed in appendix 4.

The EORP Team's main role is to operationally coordinate the project, provide support to the Committees, National Coordinators and participating centres and guard the methodological concepts of the registry.

Specifically, the EORP Team has to assure the constant quality control and continuity, necessary to ensure that projects are completed on time and within budget.

The database will be set up at the European Heart House in Sophia Antipolis, France, according to the requirements defined by the appointed Executive Committee with the support of the EORP Team. The database will be located in the European Heart House, 2035 route des Colles – Les Templiers, BP 179 – 06903 Sophia Antipolis Cedex.

7.5 Investigators sites

The investigator centres (here sites) are accepted on a voluntary basis through national coordinators, according to the criteria reported below.

The site characteristics will be described on a specific CRF. Characteristics of type, reference area and population of the selected hospital system will be collected.

The National Coordinator will supply a list of potential medical centres in his/her country that would be technically suitable to set up such a registry. The National Coordinator will be requested to outline the profile of the medical centre and to indicate whether the proposed medical centre is tertiary/community, with/without cardiac surgery, with/without interventional cardiology (CRT/ICD), with/without Heart failure

program or unit and with/without admissions of heart failure patients to internal medicine wards. The number of centres in each country varies according to its size. The choice of centres should allow for a representation of each category of hospitals in proportion to the distribution of the different types of medical centres in the individual country.

7.6 Specific selection of centres

The National Societies are requested to select a defined number of centres (i.e. one centre/2 million people, but no more than 25 per country) in their own country so as to participate in the registry.

The ratio for a country contributing 25 centres should be:

- 5 centres with cardiac surgery,
- 8 with interventional cardiology (PCI/CRT/ICD),
- 12 community centres with no surgery or interventional cardiology.

As far as possible, the centres should respect geographical criteria within each country.

The centres, in which Oversight, Executive or Steering Committees' members operate, will participate in this project *ex officio*.

Each centre will have to fill in CRFs of consecutive patients enrolled on a chosen visit day or admitted to the hospital in the same day (5 consecutive working days per trimestre). If a centre does not perform properly, it will be automatically excluded and substituted with another centre. Each centre will be rewarded with a plaque acknowledging their participation in the ESC registry, with their name reported on scientific publications according to the EORP publication policy.

8. DURATION OF REGISTRY

This registry is intended as a long-term - ideally permanent - registry. It is anticipated that approximately 10 000 patients will be enrolled within 18 months. Recruitment of further patients for the ESC-HF Long-term Registry (Phase 2) should begin in October 2013 and the 1-year follow-up should be completed in May 2016. There is no maximum number of patients per centre. The number of patients per centre, and number of centres involved in each country will be set up in advance in consultation with the National Coordinators who will have knowledge of clinical practices, specific to each country. Follow-up will be performed by the local investigators 12 months after enrolment.

9. ETHICAL ISSUES

National Coordinators in conjunction with local investigators will be responsible for obtaining the approval of the local and national review boards for this registry, if necessary.

The Scientific Secretariat and Data Management team will distribute the relevant documents in English to the National Coordinators, who will be responsible thereafter for their translation and adaptation to local standards. All patients will be approached by local centre investigators and will be asked for their written informed consent to participate in the registry (if necessary, i.e. based on local standards).

9.1 Protection of Human Subject

The ESC-HF Long-term Registry is an observational study that does not dictate the manner in which patients are evaluated or treated for acute HF/chronic HF. Physicians may decide to evaluate and manage

outpatients and inpatients with HF in the most appropriate way, according to the local standard of care. There is no selection of patients and it is necessary to obtain patients' agreement.

In case of refusal, the patient will not be enrolled in the registry (if required by national laws or regulations).

Patients' identifiable data will be stored on local computers (not in a central database) in order to facilitate subsequent follow-up of patients.

Patients dying before giving informed consent may also be included, unless the local IRB does not allow this procedure. Patients who cannot provide the informed consent at the time of admission in the cardiology ward due to very severe clinical conditions can give their consent some hours/days after admission, when more favourable clinical conditions allow them to receive the appropriate information.

Patients' data collected will be strictly anonymous. Only a code, gender, year of birth will identify patients. No other patient identifiers will be collected. In order to maintain strict security, each investigator/study personnel will have a unique login and password to enter patient's information. There will be no storage of clinical data outside of the data collection instrument, which will be a secure, web-based form. The main database will be secured according to current standards to ensure both ethical and integrity requirements of the data.

10. PUBLICATION POLICY

Data will be published under the responsibility of the Executive Committee of the study. Requests for further analyses to support ancillary publications must be submitted to the Executive Committee for review and approval. Any publication of data collected as a result of this study will be considered a joint publication by the investigator, Executive Committee members and personnel of the Scientific Secretariat and Data Management team. Authorship will be determined by mutual agreement. Contribution of the author to the study design, enrolment, data review, and manuscript preparation and review will be considered when determining the order of authorship. After the publication of the main paper, the database is available for further analyses to all participating Investigators. The Executive Committee must receive a copy of any presentation, manuscript, or abstract prior to dissemination according to the terms outlined in the protocol.

11. PROPOSED TIME PLAN

Proposed Time Plan is in appendix 5

12. REFERENCES

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Appendix 1: Executive Committee members

Marisa Crespo Leiro, Chairperson

Alexandre Mebazaa

Massimo Piepoli

Andrew Coats

Stefan Anker

Gerasimos Filippatos

Roberto Ferrari

Aldo Pietro Maggioni

Appendix 2: Oversight Committee members

Roberto Ferrari, Chairperson

Panos Vardas, President of the ESC

Michel Komajda, Past-President of the ESC

Fausto Pinto, President-Elect of the ESC

Angeles Alonso, Expert

David Wood, Expert, Representative EAPCR

Patrizio Lancellotti, Representative EACVI

Carina Blomström-Lundqvist, Representative EHRA

Jean Fajadet, Representative EAPCI

Stefan Anker, Representative HFA

Uwe Zeymer, Representative ACCA

Lieven Annemans, Health Economics/ Ex-Officio member

Aldo Maggioni, Scientific Coordinator for EORP

Luigi Tavazzi, Past-Chairman of the Oversight Committee

Appendix 3: Participating countries and National Coordinators

Participating Country	National Coordinator
Austria	Frederich Fruhwald
Bosnia and Herzegovina	Emir Fazlibegovic
Bulgaria	Plamen Gatzov
Croatia	Davor Milicic
Cyprus	Panayiotis Avraamides
Czech Republic	Jaromir Hradec
Denmark	Olav W. Nielsen
Egypt	Mahmoud Hassanein
Estonia	Tiina Uuetoa
Finland	Pekka Raatikainen
France	Damien Logeart
Georgia	Vakhtang Chumburidze
Greece	Dimitris Tousoulis
Hungary	Béla Merkely
Israel	Offer Amir
Italy	Marco Metra
Latvia	Andrejs Erglis
Lithuania	Ausra Kavoliuniene
Macedonia, FYR	Elizabeta Srbinovska, Magdalena Otljanska
Moldova	Eleonora Vataman
Poland	Jaroslaw Drozdz
Portugal	Candida Fonseca
Romania	Ovidiu Chioncel
Russian Federation	Vyacheslav Mareev
Serbia	Petar Seferovic
Slovakia	Eva Goncalvesova
Slovenia	Mitja Lainscak
Spain	Juan Delgado
Sweden	Hans Persson
Switzerland	Roger Hullin
Turkey	Ahmet Temizhan

Appendix 4: EORP Coordinating team

Thierry Ferreira, Head of Department

Gérard Gracia, Data Monitor

Emanuela Fiorucci, Assistant

Cécile Laroche, Statistician

Charles Taylor, IT specialist

Aldo Pietro Maggioni, Scientific Coordinator

Appendix 5: Proposed Registry Time Plan

Final protocol and CRF	February 2011
Commence centre recruitment	January 2011
Start of ethical committee approval process	March 2011
Investigators Meetings	March 2011
Commence recruitment of patients	March 2011

Recruitment from March 2011 to April 2013 (Phase 1)

1st and 2nd of year of recruitment	April 2013
Baseline database lock	July 2013
Results on baseline characteristics	September 2013 (ESC Congress)
Complete 1-year follow-up	April 2014
1-year-Follow-up database lock	July 2014
1-year-follow-up results	September 2014 (ESC Congress)

Recruitment from Octobre 2013 (Phase 2)

Recruitment scheme:	5 days per trimester:
	Autumn 2013
	Winter 2014
	Spring 2014
	Summer 2014
Baseline database lock	January/February 2015
Results on baseline characteristics	May 2015 (HF Congress)
Complete 1-year follow-up	May 2016
1-year-Follow-up database lock	July 2016
1-year-follow-up results	ESC Congress 2016